K103025 Page 1 of 4

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MAY 13 2011

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

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Establishment Registration Number:	9710107
Date Prepared:	October 7, 2010
Device Trade Name(s):	Given PillCam® Platform with RAPID 6.5 Given PillCam® Platform with PillCam® ESO 3 Capsules
Device Common Name:	Ingestible telemetric gastrointestinal capsule imaging system
Classification:	Regulation No: 876.1300, Class: II Panel: Gastroenterology NEZ – System, Imaging, Gastrointestinal, Wireless, Capsule NSI – System, Imaging, Esophageal, Wireless, Capsule
Predicate Device(s):	Given® Diagnostic System – RAPID Access (K060805) Given® Diagnostic System with PillCam® SB2 Capsules (K070475) Given® Diagnostic System with PillCam® ESO2 Capsules (K071153) Given PillCam® Platform with PillCam® SB2 Capsules (K090557) Given PillCam® Platform with PillCam® SB Capsules with PillCam® SensorBelt (K091405)

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General Device Description:

The Given PillCam® Platform is comprised of three main subsystems; (1) the ingestible PillCam capsule, (2) the RAPID® software, and (3) the Given® Workstation and Hardware.

1. Ingestible PillCam Capsule
The disposable, ingestible PillCam Capsule is designed to acquire video images during the natural propulsion through the GI tract. The capsule transmits the acquired images via a RF communication channel to the DataRecorder located outside the body.

2. RAPID Software
The RAPID Software is a software application that is utilized to process, analyze, store, and view the acquired images collected from the DataRecorder to create a RAPID video of the images. The software also includes a reporting function to create detailed clinical reports, in-service training videos, and patient instruction forms. RAPID 6.5 supports PillCam capsule endoscopy of the GI tract with all PillCam video capsules.

3. Given Workstation and Hardware
The Workstation is a modified standard personal computer that is the operational platform for the RAPID software. The DataRecorder is an external receiving/recording unit that receives acquired images from the capsule. The SensorArray or SensorBelt receives data from the PillCam capsule and transfers the data to the DataRecorder. The RAPID *Real Time* is a handheld device that allows for real-time viewing of acquired images through the GI tract. Other accessories include a flat panel LCD monitor, a high-capacity mass storage device, and a high-capacity USB portable storage device.

Indication for use:

1. Given PillCam® Platform with RAPID 6.5

With PillCam® SB Capsule
The PillCam Platform with a PillCam SB capsules is intended for visualization of the small bowel mucosa.

- The PillCam Platform with PillCam SB capsules may be used in the visualization and monitoring of lesions that may indicate Crohn's disease not detected by upper and lower endoscopy.
- The PillCam Platform with PillCam SB capsules may be used in the visualization of lesions that may be a source of obscure bleeding (either overt or occult) not detected by upper and lower endoscopy.
- The PillCam Platform with PillCam SB capsules may be used in the visualization of lesions that may be potential causes of iron deficiency anemia (IDA) not detected by upper and lower endoscopy.

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The Suspected Blood Indicator (SBI) feature is intended to mark frames of the video suspected of containing blood or red areas.

The PillCam Platform with PillCam SB capsules may be used as a tool in the detection of abnormalities of the small bowel and is intended for use in adults and children from two years of age.

With PillCam® ESO Capsule
The PillCam® Platform with a PillCam® ESO capsule is intended for the visualization of esophageal mucosa in adults and children from 18 years of age.

2. Given PillCam® Platform with PillCam® ESO 3 Capsule

The PillCam® Platform with a PillCam® ESO 3 capsule is intended for the visualization of esophageal mucosa in adults and children from 18 years of age.

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Technological Characteristics:	The technological characteristics are similar to the predicate devices, except for the differences that are listed in Section 13 of this submission. However, it may be concluded from the Substantial Equivalence Summary that none of the presented differences raise any new safety or efficacy issues. PillCam®ESO 3 capsule dimensions are different than the predicate device (ESO 2 capsules) and therefore the safety of PillCam® ESO 3 capsules in SIP procedure was validated. The results are presented in section 20 of this submission. It may be concluded based on the test results that the changes in the capsule's dimension do not raise new safety issues.
Bench testing:	Since PillCam® ESO 3 capsule and the predicate device are same capsules in terms of external components and technology. The biting test and pH resistance test for the predicate device are applicable for PillCam® ESO 3 capsules as well.
Performance Data:	The devices meet the guidance entitled "*Class II Special Controls Guidance Document: Ingestible Telemetric Gastrointestinal Capsule Imaging System; Final Guidance for Industry and FDA* dated November 28, 2001. The proposed changes in this submission do not raise new performance or safety issues. Since the capsule size was changed (ESO 3 capsule is longer and has larger diameter than the predicate device), the safety of size difference of PillCam® ESO 3 Capsules was validated using SIP procedure. The results are summarized in section 20 of this submission: The objective of the test was to evaluate the safety of the new PillCam® ESO 3 Capsules compared to the cleared PillCam® ESO 2 capsule. The test includes a report of 55 volunteers that underwent PillCam® ESO 3 capsules endoscopy. 53 volunteer ingested the PillCam® ESO3 capsule using SIP procedure with no reported adverse event or ingesting difficulties. Two volunteers (3.6%) faced difficulties to ingest the capsule in flat position. Once they sit up, they were able to ingest the capsule smoothly with no additional complication. The rate of difficulties is comparable with clinical study that was conducted with PillCam® ESO 2 capsules. 7% of the patients (total of 100 subjects) in the study had ingestions difficulties. It May be concluded that ingesting difficulties rate was not increased due to size change of the capsule, therefore no new safety issues were raised.
Conclusion:	Based on the technological characteristics and clinical safety of the devices, Given Imaging Ltd. believes that the Given PillCam® Platform with RAPID 6.5 and the Given PillCam® Platform with PillCam® ESO 3 Capsules and the predicate devices selected are substantially equivalent and do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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MAY 13 2011

Re: K103025
Trade/Device Name: Given PillCam® Platform with RAPID 6.5 and Given PillCam® Platform with PillCam® ESO 3 Capsule
Regulation Number: 21 CFR §876.1300
Regulation Name: Ingestible telemetric gastrointestinal capsule imaging system
Regulatory Class: II
Product Codes: NEZ and NSI
Dated: May 11, 2011
Received: May 12, 2011

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K103025

Device Name: Given PillCam® Platform with RAPID 6.5

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Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103025

Concurrence of CDRH, Office of Device Evaluation (ODE)

INDICATIONS FOR USE

510(k) Number (if known): K103025

Device Name: Given PillCam® Platform with PillCam® ESO 3 Capsules

Indications for Use:

The PillCam® Platform with a PillCam® ESO 3 capsule is intended for the visualization of esophageal mucosa in adults and children from 18 years of age.

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103025

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)